510(k) Summary

NOV 2 4 2004

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

Establishment:

- Address: Siemens Medical Solutions, Inc.
  51 Valley Stream Parkway
  Malvern, PA 19355
- Registration Number: 2240869
- Contact Person: Mrs. Ana Ladino
  Technical Specialist Regulatory Submissions
  Telephone: (610) 448-1785
  Telefax: (610) 448-1787

Device Name:

- Trade Name: X-LEONARDO
- Classification: Picture Archiving and Communications System (PACS)
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

Date of Preparation of Summary: October 20, 2004

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

- **Device Description and Intended Use:**
  This Premarket Notification covers Siemens X-LEONARDO *syngo*-based multi-modality workplace. *syngo* is a universal imaging platform based on Windows XP. The X-LEONARDO Workstation offers a comprehensive solution to view, optimize, and post-process diagnostic information and to aid the doctors in the evaluation of digital radiological examinations and patient information.

Due to special customer requirements based on the modality image type and the clinical focus, the X-LEONARDO Workstation can be configured with different combinations of clinical applications. *syngo* applications can be added to the X-LEONARDO multi-modality workplace either individually or as clinical focus packages.

The X-LEONARDO is a medical diagnostic workstation for viewing, manipulation, communication, and storage of medical images and data on exchange media.

The X-LEONARDO can be configured with a variety of *syngo*- or Windows based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available OEM applications.

- **Technological Characteristics:**
  The X-LEONARDO will be marketed as a software only solution for the end-user (with recommended hardware requirements) or as a complete workstation for the end-user (hardware and software package). It will be installed by Siemens service engineers. The X-LEONARDO Workstation described supports DICOM formatted images and information. The workstation is based on the Windows XP operating system.

- **General Safety and Effectiveness Concerns:**
  The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

  Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

- **Substantial Equivalence:**
  The X-LEONARDO Workstation, addressed in this Premarket Notification, is substantially equivalent to the following commercially available device:

  LEONARDO Workstation (K040970)

  The X-LEONARDO Workstation described in this Premarket Notification has the same intended use and similar technical characteristics as the device listed above.

In summary, Siemens believes that the X-LEONARDO Workstation does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2004

Ms. Ana Ladino
Technical Specialist,
Regulatory Submissions
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K042995
Trade/Device Name: X-LEONARDO Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 20, 2004
Received: November 1, 2004

Dear Mr. Ladino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042995
Device Name: X-LEONARDO

Indications for Use

The X-LEONARDO is a medical diagnostic workstation for viewing, manipulation, communication, and storage of medical images and data on exchange media.

The X-LEONARDO can be configured as a stand-alone diagnostic post-processing and reporting workstation.

The X-LEONARDO can be configured with a variety of *syngo*- or Windows -based software options which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques and OEM options

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042995